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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/091,665	09/02/1998	JAN ENDRIKAT	SCH1637	5200

7590

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 04/10/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/091,665

Applicant(s)

ENDRIKAT ET AL.

Examiner

Sabiha Naim Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 05 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 8-13 and 31-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-7 and 14-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 8-13 and 31-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Claims 1-35 are pending. No claim is allowed.

Applicant response in paper no. 18 is hereby acknowledged. Rejection over Neuman is withdrawn because arguments are found persuasive. Finality of the action is withdrawn due to the following reasons.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-7 and 14-30 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The term "comprising" cited in claims is inclusive and fails to exclude unrecited steps. The use of the term comprising to introduce claimed structure means that the ingredients covered by these claims may involve more elements than those positively recited. *Ex parte Gottzein* et al., 168 USPQ 176 (PTO Bd. App. 1969). Comprising leaves the claim open for inclusion of unspecified ingredients even in major amounts. *Ex parte Davis* et al., 80 USPQ 448 (PTO Bd. App. 1948).

2. Citation of "consisting essentially of" limits the scope of a claim to the specified ingredients and those that do not materially affect the basis and novel characteristics of a composition, see *Ex parte Davis*, 80 USPQ 448 (PTO Bd. App. 1948); In re Janakirama-Rao, 317 F 2d 951, 137 USPQ 893 (CCPA 1963). When Applicant contends that modifying components in the reference composition is excluded by

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recitation of "consisting essentially of" applicant has the burden of showing that the introduction of these components would materially change the characteristics of applicant's composition. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

3. Claims 4-7 are improperly dependent on claim 14. Correction is requested.
2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 14-30 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. ***.

In evaluating the enablement question, several factors are to be considered. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

- 1) The nature of the invention: The invention is directed to methods of contraception in a mammal by administering gestogen and estrogen for at least 28 days and gestogen is given in the first phase.
- 2) The state of the prior art: Various combination of estrogen, gestogen by administering in different phases are known. See prior art of record. (Gast and other references).
- 3) The predictability or lack thereof in the art: There is a general lack of predictability in the pharmaceutical art. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970).
- 4) The amount of direction or guidance present: The disclosure does present any guidance to practice the invention.

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5) The presence or absence of working examples: There is no actual working example of any in vivo, or in vitro test data which would assist the skilled artisan in practicing the claimed invention. The skilled artisan, seeking to use the invention, would be at a loss as to where to begin such discovery in the absence of such data.

6) The breadth of the claims: The claims are broad see for example claim 1 and 14.

7) The quantity of experimentation needed: Since the nature of the method is so unpredictable, and since the claims are drawn to a broad range of combinations, dosage, estrogens and gestogens, and since there is a lack of guidance present in the specification, the skilled artisan would have to undertake undue experimentation to practice the claimed invention commensurate with the scope of the claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-7 and claims 13-30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over over Gast and Koninckx (US Patent 5,747,480 and US 5,827,843) for the same reasons set forth in our previous office action.

2. Claims 1-7 and 13-30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over de Jager et al. (CA 2000438) for the same reasons set forth in our previous office action. In jager et al. estrogen is given in the first phase and combination of estrogen and gestogen in the second phase, wherein the instant case gestogen is given in first phase and gestogen and estrogen combination is given in the second phase. (See claims 4-30). In Gast reference gestogen and estrogen are given in first phase and estrogen is given in the second phase see the entire document especially claim 1. Jager teaches that large amount of progestogen is usually combined with a smaller quantity of estrogen in the preparation, see lines 31-35, page 2.

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Applicant should note that US '843 teaches administration of the preparation over a period of 3-12 months to 40. See lines 11-19, col. 3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone number is 703-305-3910. The examiner can normally be reached on First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

April 8, 2002



SABIHA QAZI, PH.D
PRIMARY EXAMINER